UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

MARY BAYES and PHILIP BAYES, Plaintiffs, v. BIOMET, INC., BIOMET ORTHOPEDICS, LLC, BIOMET U.S. RECONSTRUCTION, LLC, BIOMET MANUFACTURING, LLC f/k/a BIOMET MANUFACTURING CORP., Defendants.	Case No. 4:13-cv-00800-SRC

PLAINTIFFS' RESPONSE IN OPPOSITION TO DEFENDANTS' ADDITIONAL MOTIONS *IN LIMINE*

Plaintiffs Mary and Philip Bayes, through counsel, herby respond in one *omnibus* fashion in opposition to Defendants' Additional Motions *in Limine* at Dkt. Nos. 355 and 358.

I. Defendants have not shown a need to reconsider prior rulings.

Unhappy with the Court's MIL rulings at the September 24, 2020 pre-trial conference, Defendants now request the Court reconsider its previous rulings on Defendants' MIL No. 2s and 3. Courts in the Circuit can revisit their prior, interlocutory orders. However, a court has "an interest in judicial economy and ensuring respect for the finality of its decisions, values which would be undermined if it were to routinely reconsider its interlocutory orders." *Heubel Material Handling, Inc. v. Universal Underwriters Ins. Co.,* 4:10-CV-00102, 2011 WL 1458654, at *2 (W.D.Mo Apr. 15, 2011). The *Heubel* court, and others in the Circuit, thus have reconsidered prior rulings "only if the moving party demonstrates (1) that it did not have a fair opportunity to argue the matter previously, and (2) that granting the motion is necessary to correct significant

error." *Id.*[1] Defendants here have not made either showing. They have previously argued these evidentiary motions (so they have had an opportunity), and they have not shown any significant error the Court previously made that needs correcting. Indeed, the Court has ruled against Plaintiffs on some of their various evidentiary motions, yet Plaintiffs have not refiled motions lacking in any new law or fact for a second bite at the apple. The Court should not allow Defendants to do so, either.

II. Marketing materials are relevant and admissible in this phase, per the Court's prior ruling on Defendants' MIL No. 2. (Dkt. 358).

A. The Court's Previous Ruling.

Defendants had already submitted, and the Court denied, a motion to exclude marketing materials and references to Mary Lou Retton. The Court granted the motion for the first phase of the case, but denied it for the claim for punitive damages.

> **THE COURT:** Very good. All right. So Defendants' No. 2, the M2a-Magnum marketing materials. So assuming that the plaintiffs offer evidence that Biomet knew the M2a-Magnum was dangerous or defective, marketing materials touting the product safety or efficacy would go to show a conscious disregard for public safety. So I am denying it as a blanket prohibition on those materials, but I'll grant it insofar as there is relevance to as -- insofar as there is no relevance to punitive damages.

Sept. 24, 2020 Hr'g Tr. at 38:8-16

[1] See also, e.g., *HM Compounding Services, LLC v. Express Scripts, Inc.*, 4:14-CV-1858 JAR, 2017 WL 2118012, at *1 (E.D. Mo. May 16, 2017).

In the liability portion of the case, Plaintiffs offered a substantial amount of evidence that Defendants knew of the dangers associated with the M2a product line - so much so, a unanimous jury of ten found Defendants liable of negligence in designing the Magnum.[2] The marketing materials Plaintiffs intend to introduce show Defendants touting the safety or efficacy of the M2a line and promotion of the M2a line at the expense of the public's, including Mary Bayes's, health and safety.

Defendants' second proposition, that they be allowed to introduce the warning label to rebut conscious disregard for the safety of others, has already been deemed allowable also. Sept. 24, 2020 Hr'g Tr. at 45:24-9. The Court has already stated its position that marketing materials are admissible if they are connected to punitive damages and the warning label is admissible to rebut conscious disregard. The Court need not reaffirm its position or remind counsel of its prior rulings.

B. Defendants reliance on one case in support of their position is misplaced.

Defendants improperly read the only case cited in support of their motion, and the marketing material Plaintiffs intend to offer comports with the Court's previous ruling. After reviewing the case law, Plaintiffs will present examples of the documents used in the video depositions to turn an abstract discussion into something concrete.

The aim of punitive damages is deterrence and retribution, while compensatory damages are intended to redress a plaintiff's concrete loss. *State Farm Mut. Auto. Ins. Co. v. Campbell*, 538 U.S. 408-409 (2003). Conduct may be probative to punitive damages when it demonstrates the

[2] Plaintiffs will not regurgitate all of the evidence on this point, but instead point the Court to Plaintiffs' Trial Exhibit 7 (previously admitted and attached hereto as **Exhibit 1**) a 2003 a memorandum from Dr. Cuckler to senior Biomet executives (including Mr. Susaraba, whom Defendants plan to call live during their punitive damages case) expressing his deep concern for the entire M2a line over hypersensitivity data from a meeting in Montreal and his fear that they would all be sued.

deliberateness and culpability of defendants' actions, but the conduct must have a nexus to the specific ***harm*** suffered by plaintiff. *Id*. at 409. Defendants read *Campbell* too narrowly – they focus not on the harm, but on the legal theory to recover because of that harm. *Campbell* – nor any case after it – does not make that distinction. Under Defendants' reading of the case, a jury considering the reprehensibility of Biomet's conduct and the harm it may have caused others can only consider evidence relevant to Mrs. Bayes's underlying claims. Under Defendants' reading of the case, the jury cannot consider other evidence even though it relates to the same device and the same general injuries that people across the country suffered (indeed, there was an entire MDL relating to these suits). What the Supreme Court found objectionable in *Campbell* was the use of the individual use by various adjusters of a policy applied to many different claims. Here, that is not the issue. The device is the same and, as the Defendants argued on the point of choice of law,[3] the decisions related to the device and its design happened in a central location. This is not a device sent out around the country to distributors who then make modifications before turning the device over to doctors for implantation. In sum, Defendants misread *Campbell*, which is evidenced by the dearth of case citations in support of their "theory" of the case's holding.

Since *Campbell*, other cases have defined the admissibility of evidence in punitive damages cases. The Supreme Court has noted that "evidence of actual harm to nonparties can help to show that the conduct that harmed the plaintiff also posed a substantial risk of harm to the general public, and so was particularly reprehensible.[4]" *Philip Morris USA v. Williams*, 549 U.S. 346, 355 (2007). And since *Campbell*, the law in Missouri examines motive or reckless indifference in deciding

[3] Sept. 24, 2020 Hr'g Tr. at 53:11-18

[4] Jury Instruction MAI 10.06, which has been approved by the Court in this case notes "You may consider harm to others in determining whether defendant Biomet's conduct showed complete indifference to or conscious disregard for the safety of others. However, in determining the amount of any punitive damage award, you must not include damages for harm to others who are not parties to this case" so there is no risk in the jury considering damages from harm to others in this case.

punitive damages. *Smith v. Brown & Williamson Tobacco Corp.,* 275 S.W.3d 748, 811 (Mo. Ct. App. 2008). Courts interpreting Campbell around the nation have routinely held that marketing and the devastating public health consequences are admissible and relevant to punitive damages. *See Cote v. Philip Morris USA, Inc*., 400 F. Supp. 3d 1295, 1311 (M.D. Fla. 2019), citing *Philip Morris* at 356; *In re Prempro Prod. Liab. Litig.*,2007 WL 4189510, at *3 (E.D. Ark. Nov. 15, 2007), *objections overruled*, 2007 WL 4189497 (E.D. Ark. Nov. 21, 2007) ("advertisements must pertain to ***issues*** that are directly linked to Plaintiff, e.g. cardiac benefit, breast cancer, etc.") emphasis added citing *Phillip Morris* at 1064; *In re Wright Med. Tech. Inc., Conserve Hip Implant Prod. Liab. Litig.,* 178 F. Supp. 3d 1321, 1363 (N.D. Ga. 2016), aff'd in part sub nom. *Christiansen v. Wright Med. Tech., Inc*., 851 F.3d 1203 (11th Cir. 2017) (Plaintiffs presented evidence of misrepresentations made in Defendants' marketing materials); *In re DePuy Orthopaedics, Inc. Pinnacle Hip Implant Prod. Liab. Litig.,* No. 3:11-MD-2244-K, 2017 WL 3841608, at *5 (N.D. Tex. June 28, 2017) (finding practices Defendants used to influence physicians to use and promote their products relevant under 401 under 403); *In re Mentor Corp. Obtape Transobturator Sling Prod. Liab. Litig.,* No. 2004, 2015 WL 7863032, at *6 (M.D. Ga. Dec. 3, 2015) (marketing materials both before and after implant surgeries are admissible); *In re Testosterone Replacement Therapy Prod. Liab. Litig. Coordinated Pretrial Proceedings,* 430 F. Supp. 3d 516, 544 (N.D. Ill. 2019) (negligence claims do not necessarily require proof of reliance on marketing materials) ; *In re Testosterone Replacement Therapy Prod. Liab. Litig. Coordinated Pretrial Proceedings,* No. 14 C 1748, 2017 WL 2313201, at *2 (N.D. Ill. May 29, 2017) (finding marketing materials never viewed by plaintiffs or their physicians relevant and admissible).

Defendants try to narrowly define the harm nexus as requiring proof that Dr. Martin or Mrs. Bayes saw specific marketing materials themselves. Again, the harm nexus has been

satisfied, because the evidence deals with the M2a line of products and the same kind of soft tissue injuries. The harm nexus does not require that the legal theories related to the harm be the same in order to be admissible. The harm caused by Mrs. Bayes is the metallosis, tissue destruction, revision surgeries, and chronic dislocations caused by the M2a Magnum, and Defendants repeated representations of its safety and efficacy (and disregard of safety concerns) are certainly relevant to Defendants' conscious disregard for both Mrs. Bayes and other recipients of their M2a product line.

While Dr. Martin did not recall specific marketing pieces, he did testify that he saw Defendants' vendor representative Jake Weible on a "daily basis." Oct. 13, 2020 Tr. 57:5-10. Mr. Edgar, who Plaintiffs intend to call via prior recorded video testimony, will testify that he disseminated information to the "sales force," which would include Mr. Weible. Dr. Martin also testified that he would go to national meetings for total hip arthroplasty, and that he would read orthopedic literature and speak with other surgeons. Oct. 13, 2020 Tr. 126:4-10; 66:4-7. In essence, Dr. Martin did not operate in a vacuum. He was "drawn" to the prosthesis for its perceived benefits. Oct. 13, 2020 Tr. 56: 17-19. Biomet trained its sales force on marketing materials, and it prolifically distributed materials, like the images of two piles of wear debris, to doctors.

C. Examples of Exhibits

As Mr. Wool offered to the Court previously in person, Plaintiffs submit examples of the marketing materials that they will seek to introduce through Mr. Edgar's video deposition. These materials relate to product benefits; Biomet's flippant disregard for safety concerns; critiques of competitors for having no clinical data to support their products, which the jury should certainly consider when judging Biomet's conduct rises to the level of reckless disregard; critiques of

Biomet itself for historically having been too conservative in product launches; and critiques of shortening product lifecycles. What Biomet has said on these topics internally and externally bears directly on the question of reprehensibility of Biomet's conduct.

- **Audio File Exhibit in the Edgar Deposition**[5]: Plaintiffs intend to introduce an audio recording made by Derek Edgar, product manager for the M2a line. The recording was disseminated to Defendants' sales force and relayed "if your product is only available for seven or eight years, by the time a clinician can publish meaningful long-term follow-up data, good or bad, the product has been long since discontinued." This supports Defendants' conscious disregard for the safety of Mrs. Bayes and others who received the M2a line because Defendants are acknowledging that short product lifecycles give inadequate information regarding the safety and efficacy of products.

- **Plaintiffs' Exhibit 21**[6]: This is an internal document using WWII terminology to increase sales and is evidence that Defendants are disregarding the safety of patients in favor of sales. Profit margins on the Magnum, as shown in this document, are 71%. The document further shows that Defendants are going to great lengths to sell the Magnum, including using jet tours and fancy dinners. The profit margins, along with the push to sell them are relevant to show Defendants' motive and is relevant in the punitive damages calculus. [7]

- **Plaintiffs' Exhibit 284**[8]: This document was disseminated in the early 2000s to Defendants' sales force and advises the sales team that people who believe metal ions are a problem are akin to believers in the supernatural. The document comes nearly a decade after the 1995 consensus recognized that metal ions and debris could pose health risks and needed to be studied. Dave Schroeder, the design engineer for the M2a line testified he was aware of the consensus. Oct. 19, 2020 Tr. 33:4-16. Flippant treatment of a serious problem is relevant to the conscious disregard for the safety of patients, including Mrs. Bayes.

- **Plaintiffs' Exhibit 311**[9]: This document is an economic clinical study proposal from 2005. The document explains that Defendants are trying to justify the high cost of the Magnum by proposing a clinical study, admitting that they have nothing to justify the cost of its use. However, the proposal contains Defendants' "ideal findings" and suggests leaving most adverse events out of the reported results. This document clearly supports Defendants' conscious disregard for the safety of Mrs. Bayes and others, as it shows Defendants' motive in designing a study that reports only positive data about the Magnum and conceals

[5] Transcript of audio file attached at Exhibit 2.
[6] Attached as Exhibit 3.
[7] *Blanks v. Fluor Corp.*, 450 S.W.3d 308, 364 (Mo. Ct. App. 2014) (allowing Plaintiffs to introduce evidence, including internal documents, that defendants' decisions were profit driven); *Norman v. Textron Inc.*, 2018 WL 3199496, at *2 (W.D. Mo. May 17, 2018) (trial court allowing evidence of profit margins during punitive damages portion of trial).
[8] Attached as Exhibit 4.
[9] Attached as Exhibit 5.

evidence of revision or other adverse events. It also shows the lack of data Biomet had when it began feverishly selling the Magnum.

- **Plaintiffs' Exhibit 260**[10]: This exhibit is an internal sales script distributed to Defendants' sales force titled "Nothing Kills a Good Story like Clinical Results." The script critiques another manufacturer for failing to have clinical data in support of their product, but Defendants also did not have clinical data to support the Magnum before selling it. Defendants have set up a standard they believe manufacturers should abide by and then knowingly disregard that standard in selling the Magnum.

- **Plaintiffs' Exhibit 223**[11]: This is a PowerPoint presentation that was exhibited to Defendants' sales force. The presentation critiques Biomet for having had a "slow, measured approach" to product releases, which Biomet eventually jettisoned when it started rushing metal-on-metal hips to the market without clinical results. The second page also has a slide titled "nothing kills a good story…" This relates directly to Defendants' conscious disregard for the safety of Mrs. Bayes and others, as in designing the Magnum, Defendants have opted to throw out the slow, measured approach, which would involve more testing, because it is a weakness for sales. Defendants actively buried their head in the sand and avoided clinical results because they could kill the "good story" Biomet's marketing team created.

- **Plaintiffs' Exhibit 932**[12]: This is a PowerPoint presentation given to the sales force showing Defendants' actual knowledge of issues with the first generation metal-on-metal, including loosening/frictional torque and metal sensitivity, which is also what Dr. Cuckler warned Defendants about with the M2a line in 2003 "we're going to get sued" memorandum. The presentation is relevant to Defendants' conscious disregard for Mrs. Bayes's safety and the safety of others, as it is clear Defendants were aware of first generation issues (like loosening and sensitivity, which were issues in this 2nd generation case) but disregarded those risks.

- **Plaintiffs' Exhibit 269**[13]: This exhibit is another presentation distributed to the sales force. The "your options today" slide shows that Defendants are aware that ion release and metal sensitivity are an issue but are continuing to push sales of the M2a line.

- **Plaintiffs' Exhibit 915**[14]: This exhibit is another presentation distributed to the sales force. On the third page, Defendants are claiming "metal-on-metal will theoretically last 600 years." Here, Defendants are making an inaccurate representation of the efficacy of the Magnum, and directly relates to Mrs. Bayes's harms, as neither hip lasted more than 6 years, less than 1% of its expected lifespan.

[10] Attached as Exhibit 6.
[11] Attached as Exhibit 7.
[12] Attached as Exhibit 8.
[13] Attached as Exhibit 9.
[14] Attached as Exhibit 10.

Based on the Court's prior rulings and caselaw surrounding the issue of marketing materials as they relate to punitive damages, Plaintiffs believe that the above-mentioned examples are admissible as they are relevant to the harms Mrs. Bayes suffered and her claim for punitive damages. Defendants have presented nothing new in trying to get the Court to change its mind on this issue (and indeed only cite to *Campbell* and nothing else).

III. Post-April 28, 2008 Evidence should be admitted. (Dkt. No. 355)

In support of their proposition to exclude "post-use" evidence, Defendants cite to one case - *Campbell*. However, *Campbell* does not articulate that "post-use" evidence is not allowable. To the contrary, it confirms that the aim of punitive damages is deterrence, and the conduct must have a nexus with the harm suffered by plaintiff. *Campbell* at 408-409. As the Court has repeatedly noted, there were no intervening design changes to the Magnum. And the injuries suffered by others (implanted after Mrs. Bayes) is of the same type – soft tissue injuries from metal ions and particles surrounding the hip. So, the nexus requirement has been met.

Additionally, since *Campbell* was decided in 2003, other courts have spoken on this issue and determined that post-implant conduct is relevant to punitive damages. *See In re Mentor Corp.,* citing *Johns-Manville Sales Corp. v. Janssens*, 463 So. 2d 242, 256 (Fla. Dist. Ct. App. 1984) ("Evidence of repetition and concealment of offensive conduct after it initially occurred is indicative of malice or evil intent sufficient to support punitive damages."). Defendants, though, point to no case law going the other way in support of their reading of *Campbell.*

First, Plaintiffs disagree with the premise that only conduct pre-implantation fits within the nexus between conduct and harm and excluding this type of evidence flies in the face of deterrence. The Magnum caused metallosis, tissue and muscle destruction, chronic dislocations, and multiple revision surgeries in Mrs. Bayes. That is the harm. Evidence post-dating

implantation that relates to that harm still fits in the requisite nexus. Additionally, admitting evidence of Defendants' actions post-implantation will deter them from repeating and then concealing problems with their products. To find a different result would send a message to corporations that they can continue to conceal problems and disregard the health and safety for those already implanted with their products.

Second, Mrs. Bayes's exposure to the Magnum did not end with implantation. In fact, Mrs. Bayes's right Magnum was implanted until July 8, 2014.[15] Defendants' actions in concealing problems after Mrs. Bayes's implantation bears not only on others who suffered the same fate after her, but on Mrs. Bayes. Defendants' continued insistence that their product was safe stymied action by both Plaintiff and her physician to remove the Magnum. As evidenced by the Facebook message[16], Mrs. Bayes tried researching the Magnum, but because of Defendants' concealment of reported problems, she believed the Magnum to be safe. Plaintiffs do not intend to introduce significant amounts of Defendants' conduct post-implantation. However, Plaintiffs do intend to introduce internal e-mails where its employees received negative clinical data and made suggestions such as "closing down the lab" and "stirring up the water." [17] This e-mail was sent one year after Mrs. Bayes's implantation, while the left implant was destroying her tissue and muscle and causing her pain. Mrs. Bayes continued to suffer harm even after the left implant was removed, as shown with her elevated ion levels.

Excluding this type of evidence would allow Defendants to wash their hands of any conduct taken after April 2008, despite mounting knowledge and worsening conduct. This type of evidence satisfies the nexus between the conduct and Mrs. Bayes's harm from the Magnum and

[15] 21 CFR 803.3 mandates manufacturers to report to the FDA when they learn that any of their devices may have caused or contributed to a death or serious injury. Adverse Event data is then publicly available.
[16] See Exhibit 11.
[17] See Exhibit 12.

excluding this evidence would detract from the purpose of punitive damages – deterrence for reprehensible conduct relating to the Magnum that caused soft tissue damage for patients, including Mary Bayes.

Simply put, Biomet's reprehensible conduct relating to the Magnum (concealing the extent and nature of harm it could cause) continued after Mrs. Bayes had her implants; it was the same device, and it continued causing the same type of harms in patients who got it after her. That is all that is required for the *Campbell* harm nexus, and Defendants cite to nothing requiring more.[18]

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The Court's prior rulings on these issues are more than sufficient for the Parties to move forward and work out issues relating to evidence, and Defendants have not pointed to any new law, any new facts, or any manifest error by this Court that needs correcting. Based on the aforementioned, Plaintiffs respectfully request the Court deny Defendants' Additional Motions *in Limine* at Dkt. Nos. 355 and 358.

Dated: October 28, 2020.

Respectfully submitted,

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[18]There is no potential for jury confusion in having to limit or ignore the post-implant bad conduct evidence when deciding the issue of negligence, because that has already been decided given the bifurcation.

CERTIFICATE OF SERVICE

I hereby certify that a copy of the above and foregoing has been served on all counsel of record by electronic transmission on October 28, 2020.

/s/ Darin L. Schanker
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